

REMARKS

Claims 23, 25-43, 45-48, 50, 52-55 are pending in this application.

At page 3 of the office action, Claims **23**, 26-28, 30-35, **37-44**, 46-48, **50**, and 53-55 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam or Volicer, in view of McNally.¹

At page 4 of the office action, Claims **43-48**, **50**, and 52-55 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pars in view of McNally.

Applicants respectfully traverse the obviousness rejections.

The Examiner's theories and assumptions only stated a rebuttable *prima facie* case of obviousness. However, Applicants have rebutted that *prima facie* case of obviousness, and it is legally impermissible for the Examiner just to return to his own rebuttable assumptions after they have been properly rebutted by Applicants with evidence.

From the final office action, it seems that the Examiner has no specific point of disagreement with any of Applicants' submitted evidence. For example, the Examiner in the final office action has not stated even one sentence or phrase in the Declaration of Dr. Weer dated 27 March 2006 with which he disagrees or takes any issue.

The obviousness rejections are based on an assumption by the Examiner (page 5) that a person of ordinary skill in the art would have been motivated to prepare THC formulations using HFA propellants instead of CFCs because CFCs were being phased out in favor of propellants, such as hydrocarbons, which were known to be less harmful to the ozone layer. That assumption has been rebutted by Applicants' submitted evidence. The Examiner has not directly challenged any of Applicants' submitted evidence. It is not proper for the Examiner to simply return to his basic underlying assumption when Applicants' evidence shows to the contrary. The evidence of record is that: "One of ordinary skill in the art would have recognized that

¹At page 3 of the office action, dependent Claim 36 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam, Volicer, Nally, and the 1997 "Appetite Stimulation" reference. At page 8 of the office action, dependent Claims 25, 45, and 52 have been rejected over Mechoulam, Volicer and McNally, further in view of Pars. Claims 25, 45 and 52 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam, Volicer, McNally and Pars. Claim 29 has been rejected over Mechoulam, Volier, McNally, and Ohlsson.

solubilizing drugs in HFA propellants is a difficult and challenging hurdle in the preparation of acceptable MDI formulations. It would be particularly surprising and unexpected to one of ordinary skill in the art that the solubility of THC in HFA propellants is high.” (Dr. Weers Declaration, paragraph 4.) This evidence particularly cannot be ignored or given low weight by the Examiner because Dr. Weers has explained why in scientific detail, and the Examiner has not disagreed with any of the underlying scientific reasoning and detail in Dr. Weers’ Declaration (pages 2-9).

At page 5 of the final office action, the Examiner discusses the primary McNally reference and respirable fraction. The McNally reference fails to teach or disclose THC. As Applicants’ evidence shows, THC poses special challenges and problems, and a reference’s disclosure about how to work with a non-THC substance is not pertinent.

At pages 5-6 of the final office action, the Examiner cites Radhakrishnan USP 5,192,528 and Burns USP 5,284,133. Radhakrishnan concerns corticosteroid drugs, which are, e.g., aldosterone, beclomethasone, betamethasone, budesonide, cloprednol, cortisone, cortivazol, deoxycortone, desonide, dexamethasone, difluorocortolone, flucolorolone, fluorocortisone, flumethasone, flunisolide, fluocinolone, fluocinonide, fluorocortolone, fluorometholone, flurandrenolone, fluticasone, halcinonide, hydrocortisone, meprednisone, methylprednisolone, paramethasone, prednisolone, methylprednisolone, prednisone and triamcinolone – not THC. Note that Burns only generally concerns MDIs and patient compliance, and fails to teach or disclose working with THC. Burns states: “Examples of the types of drugs which have been routinely provided by these aerosolizing devices include: β -agonists such as albuterol (salbutamol), isoproterenol, ephedrine, epinephrine, salmeterol, terbutaline; corticosteroids such as triamcinolone acetonide, beclomethasone dipropionate, dexamethasone, and aldosterone; allergic mediators such as cromclyn sodium; antibiotics; and anticholinergics.” What Radhakrishnan and Burns were disclosing for non-THC substances is not pertinent; the Declaration of Dr. Weer clearly explains THC as a problem case, not susceptible of generalizations about other substances, and it is not legally permissible for the Examiner to ignore this evidence specific to THC and return to incorrect generalizations which are at odds with the knowledge and background of a person of ordinary skill in Applicants’ art at the time of

the invention.

The *prima facie* case of obviousness has been rebutted by Applicants. The Examiner has disagreed with not even a sentence in the submitted Declaration of Dr. Weer. It is legally impermissible for the Examiner to return to his rebutted *prima facie* obviousness position.

Wherefore, reconsideration and withdrawal of all the obviousness rejections are respectfully requested.²

At page 4 of the office action, Claims 26-29, **43**, 44, 46, 48, **50**, and 52-55 have been rejected for nonstatutory obviousness-type double patenting based on claims 1-12 of U.S. Patent No. 6,509,005.

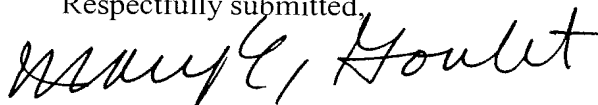
This issue will be addressed in due course by filing a Terminal Disclaimer.

In view of the foregoing, it is respectfully requested that the application be reconsidered, that claims 23, 25-43, 45-48, 50, 52-55 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephone or personal interview.

A provisional petition is hereby made for any extension of time necessary for the continued pendency during the life of this application. Please charge any fees for such provisional petition and any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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²For simplicity and brevity, further comments about dependent claims are not provided at this time.